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10/539,021	01/30/2006	Yukoh Sakata	19331-002US1 OSP-18070	7382
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EXAMINER SASAN, ARADHANA				
ART UNIT		PAPER NUMBER		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PATDOCTC@fr.com

Office Action Summary

Application No.

10/539,021

Applicant(s)

SAKATA ET AL.

Examiner

ARADHANA SASAN

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5, 7, 11 and 14-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5, 7, 11 and 14-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S5108)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Application

1. The remarks, amendments, and Request for Continued Examination filed on 03/10/09 are acknowledged.
2. Claims 1-4, 6, 8-10, 12-13 and 19-20 were cancelled. Claim 5 was amended.
3. Claims 5, 7, 11 and 14-18 are included in the prosecution.

Continued Examination under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/10/09 has been entered.

Response to Arguments

Rejection of claims 5, 7, 11 and 15-18 under 35 USC § 102(b)

5. In light of the amendment of claim 5, Applicants' arguments, see Page 4, filed 03/10/09, with respect to the rejection of claims 5, 7, 11 and 15-18 under 35 USC § 102(b) as being anticipated by Iwata et al. (WO 01/40182 A2) have been fully considered and are found persuasive.

Therefore the rejection of 12/11/08 is withdrawn. However, upon further consideration, a new ground(s) of rejection is made over Butler (US 3,049,433) and over Butler (US 3,049,433) in view of Iwata et al. (WO 01/40182 A2).

Rejection of claim 14 under 35 USC § 103(a)

6. In light of the amendment of claim 5, Applicants' arguments, see Page 4, filed 03/10/09, with respect to the rejection of claim 14 under 35 USC § 103(a) as being unpatentable over lwata et al. (WO 01/40182 A2) have been fully considered and are found persuasive.

Therefore the rejection of 12/11/08 is withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of Butler (US 3,049,433).

Response to Declaration

7. The declaration filed 03/10/09, by inventor Yukoh Sakata, has been fully considered. The declaration describes the results of tests regarding the film formation between a composition disclosed by lwata and a composition based on the instant application. The declarant uses a film comprising HPMC and calcium carbonate as the lwata composition. However, lwata also discloses that the water soluble calcium salt, calcium sulfate, can be added into a coating agent in order to protect from light (Page 24, lines 19-24). Therefore, the comparison in the Declaration is not commensurate in scope with the film composition disclosed by lwata.

However, in light of the amendment of claim 5 to recite the limitations of the water-soluble calcium salt "selected from the group consisting of calcium chloride, calcium lactate, and calcium gluconate", the Declaration is persuasive since lwata does not disclose calcium lactate, calcium chloride or calcium gluconate.

The rejections of 12/11/08 are withdrawn.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 5, 7, 11 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Butler (US 3,049,433).

The claimed invention is a film-forming composition comprising a calcium-containing compound and a film-forming base agent, wherein the calcium-containing compound is a water-soluble calcium salt selected from the group consisting of calcium chloride, calcium lactate, and calcium gluconate and the film-forming base agent is a water-soluble cellulose base polymer.

Butler teaches film compositions where a stabilizer is incorporated into a cellulose derivative to eliminate or minimize the discoloration of the cellulose derivatives (Col. 1, lines 38-41). The "...cellulose derivative and stabilizer were mixed together ... and films were cast from the mixture and dried" (Col. 1, lines 62-67). Table 1 summarized the examples and includes calcium chloride at 5.0 percent (Col. 2, lines 50-69). All percentages were by weight and "the percent stabilizer is by weight of the cellulose derivative and both are on a dry basis" (Col. 2, lines 1-4). Percent light transmission through each of the films was determined (Col. 2, lines 14-15). Butler teaches that "very small amounts of stabilizer are effective ... the examples show stabilizing with as little as 0.5% and as high as 10% stabilizer" (Col. 5, lines 19-27). "The

compositions (i.e., the mixture comprising the cellulose derivative, stabilizer and solvent for the two) are particularly useful where it is desirable to lay down a deposit, coating or film and evaporate the solvent therefrom ..." (Col. 5, lines 32-38). Water soluble cellulose ethers that can be used in the film compositions including hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers are disclosed (Col. 5, lines 42-53). Water soluble stabilizers are also disclosed (Col. 5, lines 47-48).

Regarding instant claim 5, the limitation of a film forming composition comprising a water-soluble calcium salt selected from the group consisting of calcium chloride, calcium lactate and a water-soluble cellulose base polymer is anticipated by the film forming composition (Col. 1, lines 62-67) comprising water soluble stabilizers (Col. 5, lines 47-48) such as calcium chloride (Col. 2, lines 50-69) and water soluble cellulose ethers including hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers (Col. 5, lines 42-53), as taught by Butler.

Regarding instant claim 7, the limitation of the calcium-containing compound that is provided in a light-shielding agent is anticipated by the calcium chloride taught by Butler (Col. 2, lines 50-69). The instant specification discloses that that "a light-shielding agent contains at least one calcium containing compound" (Page 3, lines 2-6).

Regarding instant claim 11, the limitation of the film-forming base agent is anticipated by the water soluble cellulose ethers including hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers (Col. 5, lines 42-53), as taught by Butler.

Regarding instant claim 14, the limitation of the calcium salt in an amount of 0.1 to 150% by weight, relative to a weight of the film-forming base agent is anticipated by the 5.0 percent of calcium chloride taught by Butler (Col. 2, lines 50-69).

Therefore, the limitations of claims 5, 7, 11 and 14 are anticipated by the teachings of Butler.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claims 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Butler (US 3,049,433) in view of Iwata et al. (WO 01/40182 A2).

The teaching of Butler is stated above.

Butler does not expressly teach a formulation (tablet, granule or capsule) coated with the film-forming composition.

Iwata teaches a solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17). Iwata teaches polymeric film coating of the tablets where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Iwata also teaches that "in order to protect from light or to improve the discriminability, a suitable

coloring agent may be added into a coating agent. Calcium sulfate (a water soluble calcium salt) is disclosed as a coloring agent that may be used (Page 24, lines 19-24).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make a film composition with a water soluble cellulose ether (such as hydroxypropyl cellulose and alkyl hydroxyalkyl cellulose ethers) and a water soluble stabilizer (such as calcium chloride), as taught by Butler, substitute it for the film coating composition that coats dosage forms such as tablets, granules and capsules, as taught by Iwata, and produce the instant invention.

One of ordinary skill in the art would do this because Butler teaches that the film composition is particularly useful where it is desirable to lay down a deposit, coating or film (Col. 5, lines 32-38) and Iwata teaches the film coating of commonly used dosage forms such as tablets, granules and capsules (Page 22, lines 14-17). One of ordinary skill in the art would have a reasonable expectation of success in producing a functional tablet/granule/capsule with a film coating comprising a water-soluble cellulose ether and a water-soluble calcium salt.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Regarding instant claims 15-18, the limitation of a formulation with the film-coating composition would have been obvious over the teaching by Iwata that the solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17) and polymeric film coating where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Regarding the limitation of coating by a spraying method, it would be obvious over the spraying of hydroxypropylcellulose, as taught by Iwata (Page 42, lines 4-9).

Conclusion

13. No claims are allowed.
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615